cover the required extension fee. The Assistant Commissioner is hereby authorized to charge any additional fee which may be due in connection with this Petition to Deposit Account No. 23-1703.

REMARKS

Claims 1-6, 12 and 14-29 remain pending in the application.

The Office Action consists solely of a Restriction Requirement. The Examiner has invoked PCT unity of invention criteria, asserting that the embodiments of the invention encompassed by the claims are not linked by a common special technical feature. The Examiner's reasoning is that each polymer matrix encompassed by the claims has "a unique special technical Feature because each polymer possesses unique properties based on its structure." The Examiner concludes that "one ultimate polymer matrix" must be elected for examination.

In response, Applicants provisionally elect the polymer matrix material polyethylene oxide, as exemplified in instant Example 1. This material is an eroding matrix material and is one of several preferred (but certainly not exclusive) eroding matrix materials, including hydroxypropyl methyl celluose and paraffin (see, e.g., page 8, lines 24-28 of the instant specification). Applicants wish to emphasize that polyethylene oxide is merely selected as one species of the "polymeric matrix" genus in response to the restriction requirement. This election is not to be taken in any way as an acknowledgment that said species is the only matrix material suitable for use in the presently claimed invention nor as an acknowledgment that

restriction of any kind is proper. This election is made with emphatic traverse.

In the first place, the present application, as a CPA, is considered by the PTO to be a new (i.e., "continuing") application. MPEP §1895.01(D) states, inter alia: "[a] continuing application claiming benefit ... to an international application or to a national stage application is not a national stage application and, therefore, the restriction practice under 35 U.S.C. 121 is applicable." Accordingly, PCT unity of invention criteria should not have been invoked in the Office Action.

Having said this, however, Applicants also would like to point out for the record that, even if unity of invention criteria were applicable in this instance, such criteria could not be said to justify restriction of the presently claimed subject matter. In fact, all of the presently claimed embodiments of the invention do have a common special technical feature. Regardless of the polymeric matrix material used, regardless of whether this is a single matrix or a combination of matrices, and whether or not each matrix material is identical in all its properties to all other contemplated matrix materials, all of the claimed compositions share the surprising feature that they provide sustained release of a highly water-soluble salt of fluvastatin. Applicants further note that, upon proper application of unity of invention criteria, the International Preliminary Examining Authority found the claimed subject matter to constitute a single invention; in fact, said subject matter is

even broader in scope than that presently pending in the instant application.

On September 7, 2001, the Examiner and Applicants' agent discussed this issue. The Examiner suggested the possibility that, should PCT unity of invention criteria prove inapplicable, he might well turn to U.S. restriction practice as the basis for leveling a new Restriction Requirement. In anticipation of such a response, Applicants wish to address the following remarks to the inappropriateness of such an action on the Examiner's part.

The present claims are directed to pharmaceutical compositions and methods employing said compositions. Presumably, then, should the Examiner invoke U.S. restriction practice, he would invoke MPEP §806.05(h) in particular as the basis. One of the criteria to be applied in such an analysis is whether the claimed method can be practiced with another materially different product. While the Examiner might like to assert that such is the case in this instance, it should be pointed out that the present invention represents a great improvement, as clearly set forth in the specification, over previously known formulations. While it may be true that other means, such as large amounts of slow-release excipients and/or an osmotic-pressure-controlled formulation, can be used to achieve sustained release, such means are less desirable for reasons also set forth in the instant specification. Furthermore, and surprisingly, the present compositions comprise a highly water-soluble active agent which can be released slowly without the use of such undesirable means. Thus, it would not be appropriate

simply to make the assertion that other means are available for achieving the effect; it must be recognized that the presently claimed means is surprising in its effectiveness and is superior and, thus, that the product-and-process-of-using relationship is irrelevant.

With respect to the second criterion to be applied in such a case as the present one, there is no evidence that the presently claimed product, i.e., a composition containing a water-soluble salt of fluvastatin and a polymeric matrix formulation comprising at least one polymeric matrix material, can have any significant utility in a "materially different process." In fact, as is made clear in the specification and iterated above, even the fact that the instant compositions are useful in the instantly claimed method is surprising. It is the Examiner's burden to provide support for any assertion of utility in a materially different process, and it is Applicants' contention that such support is not available.

In the September 7th telephone discussion, the Examiner also suggested the possibility that an "undue burden" argument might be used in support of a Restriction Requirement. In this regard, Applicants note that the Examiner did not even attempt to restrict the claimed subject matter in the parent application and found it no burden to examine the totality of subject matter claimed at that time. Applicants further note that the claims as presently amended encompass a narrower scope of subject matter than did the claims examined in the parent application; in original claim 1 the material in which the active agent was to be

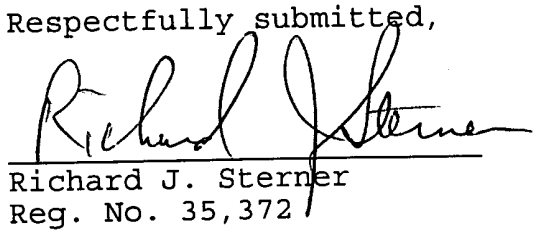
formulated was "selected from the group consisting of matrix formulations, diffusion-controlled membrane coated formulations and combinations thereof," while present claim 1 recites that the material in which fluvastatin is to be formulated is "a polymeric matrix formulation comprising at least one polymeric matrix material." Clearly, then, there is considerably less of a burden on the Examiner in the instant case than there was in the parent application, and no search beyond that already performed by the Examiner is required. In any event, an assertion of undue burden would not constitute a reasoned basis for leveling a Restriction Requirement in the present case.

For all of the reasons set forth above, neither the presently invoked PCT unity of invention criteria nor the requirements of U.S. restriction practice can be seen as effective bases for leveling a Restriction Requirement. It is respectfully requested that the present Restriction Requirement be withdrawn and that the Examiner consider the presently claimed subject matter in its entirety on the merits.

The Assistant Commissioner is hereby authorized to charge any fees which may be due for any reason to Deposit Account No. 23-1703.

Dated: October 18, 2001

Respectfully submitted,



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